

Application No. 09/763,822
Paper dated June 1, 2005
In response to USPTO correspondence of December 1, 2004
Attorney Docket No. 702-010272

REMARKS

Claims 43, 45-65, 69 and 71-86 are currently pending in this application. Claims 64, 65 and 75 have been amended. No new matter has been added. In view of these amendments and of the following remarks, Applicants believe that all of the asserted rejections are in condition for withdrawal and all of the claims are in condition for allowance.

The Examiner states that Applicants have misinterpreted the Examiner's position by stating that method claims 69 and 71-74 which recite the DNA of SEQ ID NO: 13, will be rejoined as a matter of right and that claims 72-74 are not method claims as they are drawn to a "source of artemisinin," and thus cannot be included in any rejoinder to the currently prosecuted product claims. Applicants point out that withdrawn claims 69 and 71 are method claims and, according to MPEP § 821.04, Applicants are encouraged to present process claims which include all of the limitations of the patentable product in the application at an early stage of prosecution in order to expedite prosecution, and such process claims will be entered as a matter of right if presented prior to final rejection or allowance. Applicants respectfully request, therefore, that method claims 69 and 71 be entered for examination.

Claims 64-65 and 75 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of written description. The Examiner asserts that the specification only provides for the expression of a single plant DNA construct of SEQ ID NO: 13 in *Escherichia coli*, and that there is no description of either expression of parts of host cells and/or details of obtaining transformed tissue or an organism, which may be a human tissue or human, and thus without such a description, extending the teachings of a single species construct of SEQ ID NO: 13 in *E. coli* to a genus expressing such DNA in any tissue or organism is lacking written description for the genus. Claims 64 and 65 have been amended to recite a transgenic plant tissue and transgenic plant organism, respectively, and the phrase "part of" has been deleted from both claims. Additionally, claim 75 has been amended to recite a non-human transgenic cell, tissue or organism. Support for the phrase "non-human" is found inherently throughout the specification in that only plants, bacteria and yeast are discussed for the isolation, characterization and expression of amorphaadiene synthase in transgenic cells, tissues and organisms. Further, inherent support for the phrase "non-human" is provided in Examples 1 through 8, which

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provide working examples of the isolation, characterization and expression of amorphadiene synthase in transgenic cells, tissues and organisms in plants, such as *A. annua* and *N. tabacum*; in bacteria, such as *E. coli*; and in yeast, such as *S. cerevisiae* and *P. pastoris*. Applicants submit, therefore, that based on the amendments of claims 64, 65 and 75, the written description rejection has been obviated.

Claims 43, 45, 47-65 and 75-86 stand rejected under 35 U.S.C. 112, first paragraph, for purported lack of enablement. The Examiner asserts that, although the specification is enabling for an isolated DNA sequence of SEQ ID NO: 13 encoding a synthase of SEQ ID NO: 14, it does not provide enablement for a DNA sequence that is 70-95% identical to SEQ ID NO: 13. Applicants respectfully submit that it is a standard practice in the art to generate homologous fragments of known nucleic acid sequences and to then routinely test the proteins translated therefrom for a particular activity, and that such a standard practice is required for all protein products. Therefore, contrary to the Examiner's assertion, testing a protein's activity is customary and thus is not undue experimentation. Indeed, with respect to Accession No. AF327526, one would not expect that all homologous fragments, even homologous fragments with a 98.6% homology to SEQ ID NO: 13, would have the activity of SEQ ID NO: 13, as it would be expected that a certain percentage of protein products would be inoperable. The testing for a protein's activity is, therefore, an integral part of generating a homologous fragment, which needs to be done in any case, and thus would not be considered undue experimentation.

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For all the foregoing reasons, pending claims 43, 45-65, 69 and 71-86 are patentable and in condition for allowance. Withdrawal of the asserted rejections and allowance of all pending claims 43, 45-65, 69 and 71-86 are respectfully requested.

Respectfully submitted,

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